JUL 1 8 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K081619

A. Submitter:

Chromogenex Technologies Limited
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Great Britain

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Contact: Mr Peter R Bevan (Quality Manager)

Date Prepared: 30th April 2008

B. Device Names:

Classification name	Laser Surgical Instrument 21 C.F.R 878.4810
Common/usual name	Chromolite - Intense Pulsed Light (IPL)
Proprietary name	Chromolite™ EP

C. Predicate Device: Chromolite™ System

D. Device Description:

The Chromolite™ EP System is an Intense Pulsed Light-based medical device utilising xenon flashlamp technology to illuminate, to offer light based therapies as listed in the indications for use. The Chromolite™ EP System emits light at 390nm to 1200nm via a 50mm x 15mm waveguide at a repetition rate of up to 0.5Hz.

E. Intended Use:

Indications for use for Fitzpatrick skin types (I to V).

The Chromolite™ EP System is intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostatis of soft tissue in the medical specialities of plastic surgery and dermatology as follows:-

Indications for use for Fitzpatrick skin types (I to V).

- The treatment of moderate inflammatory acne vulgaris
- The treatment of benign pigmented epidermal lesions including dyschromia, hyper-pigmentation, melasma, ephelides (freckles)
- The treatment of cutaneous lesions including warts,scars, and striae.
- The treatment of benign cutaneous vascular lesioins, including port wine stains, hemamangiomas, facial, truncal, and leg telangiectasias,erythema of rosacea,angiomas, and spider angiomas, poikiloderma of civatte, leg veins and venous malformations.
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction.

1 = Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regimen.

F. Comparison with the Predicate Device:

The Chromolite™ EP System is a hardware and software modification of the previously cleared Chomolite™ System. The Chromolite™ EP and the Chomolite™ System have the same intended use and use the same operating principle.

Based on the data and information presented here, the Chromolite™ EP System is substantially equivalent to the Chomolite™ System currently manufactured and distributed by Chromogenex Technologies Limited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Chromogenex Technologies Limited
% Mr. Peter R. Bevan
Quality Manager
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Carmarthenshire SA14 8QG
Great Britain

JUL 18 2008

Re: ~~K081619~~
Trade/Device Name: Chromolite™ EP System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 23, 2008
Received: July 7, 2008

Dear Mr. Bevan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at ~~(240) 276-0115~~. ~~Also, please note the regulation entitled, "Misbranding by reference to~~ premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081619

Device Name: Chromolite™ EP System

Indications for use for Fitzpatrick skin types (I to V).

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- The removal of unwanted hair and to effect stable long-term or permanent hair reduction.

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Prescription Use __X___ AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081619